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To: Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm 1061
Rockville MD 20857

re: 98N-1170, docket number for the tanning salon warning-label debate

Dear Dr Cyr

As you may recall, I spoke on the subject of the relative skin cancer risks of both balanced UVA-UVB and unbalanced UVA-only light at the N.I.H. Research Workshop on the Risks and Benefits of Ultraviolet Radiation and Tanning which was held on the N.I.H. campus in Bethesda last September 16-18, 1998.

From my discussion, you will perhaps remember that I grouped sunscreen use and "high-pressure" UVA-only tanning light use together because they both allow a person to get a much larger dose of melanoma-implicated UVA light than a person could normally tolerate if that light contained the usual 2-10% of UVB. I argued that we need to do something about the melanoma risk of sunscreens because routine sunscreen users have been documented to be at increased risk for melanoma, and because the incidence of melanoma has gone up 8-fold or thereabouts since sunscreens were introduced and their use expanded.

This is not a theoretical risk. There is dramatic loss of life and dramatic increase in morbidity associated with sunscreen use.

Tanning lamps, on the other hand, are only associated with a hypothetical risk--to my knowledge, there has been no increased incidence of melanoma demonstrated in tanning lamp users. Moreover, as I pointed out in my talk and the article that was submitted for the Proceedings of the Workshop, a broad view of the research would only be able to hypothetically implicate the high-pressure UVA-only tanning lamps as possibly being a factor in melanoma production, because the low-pressure balanced UVA-UVB lamps do not allow excessive UVA exposure within the limits of non-burning exposure. High-pressure UVA-only tanning lights are a small portion of tanning units in this country, so requiring a warning label on all tanning units would be grossly unfair because such a label could only possibly be appropriate for the "high-pressure" UVA-only units.

Skin goes through several protective processes when there is regular repetitive exposure to UV light. These protective processes are quite specific to the wavelength of the repetitive exposure. When the body has time and familiarity to adapt to UVA exposure, as it does in the case of a tanning-facility user, that exposure is much less damaging than the massive UVA exposure on unaccustomed skin that pale persons from Seattle experience when they go to Hawaii in February, slather on the SPF 40 (that probably only has a UVA SPF of 2-3), and get15 times the melanoma-producing UVA dose that they could normally tolerate without burning. It is small wonder that we see massive epidemiological implication of sunscreens in the production of melanoma, but little or none in the tanning-salon users who get regular exposure on thoroughly-tanned UVA-accustomed skin.

Those who advocate the regulatory pejoration of tanning salons invariably speak from a narrow view of the available research, conveniently ignoring the lack of epidemiological melanoma trends in real populations of tanners. These same people also conveniently ignore the very large epidemiological melanoma trends in routine sunscreen users. This regulatory zeal is totally misplaced. It should start with warning labels on sunscreens, and perhaps someday be extended to high-pressure UVA-only tanning lamps if the research then supports such a move. Such regulatory labeling should definitely never be applied to the standard garden-variety UVA-UVB tanning unit, which in all probability provides actual resistance to melanoma in much the same way as routine UVA-UVB sun exposure in outdoor workers has been documented to decrease melanoma incidence in these populations.

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I am including hereafter an excerpt from the text of my paper for the Proceedings of last September's N.I.H. Workshop on UV Light, which will further discuss this issue. References in this excerpt that refer to other science articles are directly following the excerpt:

Unbalanced ultraviolet light—when the abundant longer-wavelength less-powerful ultraviolet A rays are not accompanied by enough of the scarce shorter-wavelength more-powerful ultraviolet B rays—has been associated in three separate circumstances with increased cancer death rates. Our most familiar experience with this ultraviolet-B-deficient light comes during the autumn and winter in temperate climates when the sun becomes so low in the sky and weak at mid-day that it cannot burn or make vitamin D in human skin. This period varies with each geographic location, and has been aptly termed "vitamin D winter" (44). Average death rates for the four documented sun-inhibited cancers vary from 15% to 19% lower (8) in the three states (Arizona, New Mexico and Hawaii) that have no vitamin D winter in any part of their territory (35), which suggests that approximately 28,000 U.S. lives yearly (1) are lost to cancer death as a result of Vitamin-D Winter, when the UVA-only light fails to work through the vitamin D pathways as balanced UVA-UVB lght would do during the remainder of the year.

The total effect of Vitamin D Winter on cancer death rates appears to be poorly understood, since total deaths from all cancers average 14.7% lower in our three sunniest states than in the U.S. overall (8), which translates into 83,000 U.S. deaths per year (1) that appear to be a consequence of living in the less-sunny states. This is much more than can be calculated using data from known effects on the documented sun-inhibited cancers, suggesting that Vitamin D Winter has a much greater effect on cancer death rates than can presently be explained through known mechanisms and identified vitamin-D-inhibited cancers. Obvious possible explanations for this include vitamin-D-inhibited cancers yet to be identified and/or action pathways other than vitamin D metabolism.

Ultraviolet-B-deficient light is also produced in areas where sulfur-bearing acid haze air pollution selectively screens out the ultraviolet wavelengths that would produce vitamin D, creating a situation in which the angle of the sun must be higher in the sky, and the distance of atmospheric penetration must be shorter, for meaningful penetration by vitamin D rays. This extends the duration of Vitamin D Winter and makes time-of-day more critical during seasons when vitamin D light is available. This has been associated with increased rates of breast and colon cancer (5,42), and would presumably have the same effect on prostate and ovarian cancer rates.

Even more efficiently than polluted air, sunscreens also remove ultraviolet B from the light that strikes our skin (6,7). This is done to prevent sunburn, but has the accidental effect of lowering vitamin D blood levels (45). Blood 25-hydroxyvitamin-D3 levels below 20 ng/ml have been associated with a tripling increase in colon cancer rates (29) and also a lesser but quite substantial increase in prostate cancer rates (32), and would presumably have a similar relationship with breast and ovary cancer.

Surprising to some, sunscreens apparently increase skin cancer risk. Several studies show increases in both melanoma and the basal form of nonmelanoma skin cancer, and none have shown any decrease in these cancers through sunscreen use in humans (6,7,46-48). Additionally, the temporal symmetry of increased skin cancer rates following along some years after the power and prevalence of sunscreens increased argues strongly that sunscreens are the cause of the current skin cancer epidemic, rather than the cure (6,46,48). In animals, only squamous cell carcinoma (arguably the least-significant skin cancer) has been demonstrated to be prevented through the use of sunscreens (49), and the spectral character of most lamps used in these studies are so unrepresentative of the light that human skin encounters in nature or tanning salons as to make the value of these studies questionable (50).

This counter-effectiveness of sunscreens in regard to skin cancer appears to result from the fact that most sunscreens are very good at excluding the burning UVB rays, but quite poor at excluding the seldom-burning but seriously-carcinogenic UVA rays. UVA light appears to be a greater cancer melanoma danger than UVB because it constitutes 90-95% of ultraviolet light, and because it penetrates deeper and is therefore more likely to produce cancer in the deeper-lying melanocytes, whereas UVB expends its energy in shallower tissues and generally produces only seldom-fatal squamous cell skin cancer (6,7,46-48).

A person with pale skin can go to Hawaii in February, rub on an SPF 40 lotion (which, if there were such a rating, would have an SPF of 2 or 3 for UVA), go out in the sun for, say, 36 times longer than his skin would normally tolerate, and get 12-18 times more melanoma-causing UVA than he would normally be able to tolerate. UVA also is much less effective at promoting the skin thickening and tanning that usually result quickly from repeat non-burning UVA-UVB exposure, so sequential exposures to UVA do not become less harmful nearly as quickly as do balanced UVA-UVB exposures (6,7,46,48). By removing the exposure-deterring risk of burning, and greatly diminishing the process of skin accommodation, sunscreens create and facilitate the classic circum-

stances for melanoma initiation and progressionrepetitive exposure to carcinogenic deeply-penetrating UVA light at intensities and durations far greater than that for which the skin is accustomed (6,7,46,48).

All of these factors help to explain why melanoma and nonmelanoma skin cancer rates have gone up as sunscreen use has gone up (6,7,46,48). However, sunscreens apparently would not be a health hazard if they blocked UVA and UVB equally, and carried a warning label of the decreased vitamin D risks and increased internal cancer risks that go with routine use (unless supplementation steps are taken to replace lost opportunities for vitamin D photosynthesis).

Ultraviolet-B-deficient light is also to be found in those tanning facilities that use high-pressure lamps. This appears to be the least risky of the unbalanced ultraviolet exposures because it does not prevent a person from making vitamin D during sun exposure when away from the salon, and therefore shows minimal potential for raising death rates from internal cancers. The filters routinely used in front of these high-pressure lights remove virtually all of the ultraviolet B wavelengths from the exposure. Since the higher-energy ultraviolet B rays are more effective for tanning, their removal results in 2-6 times as much melanoma-implicated UVA being required to get the desired tanning effect (51). However, the risk is probably slight due to the regularity of exposure stimulating both visible (tanning) and invisible (as demonstrated by accommodated lip-tissue burn-resistance) skin protection from UVA damage. The main detriment in these UVA-only tanning systems is clearly (as in the case of sunscreens) th loss of vitamin-D-synthesis opportunities and the consequent decreased resistance to highly-fatal cancer that derives therefrom. It is ironic, though, that (like the sunscreens they imitate) high-pressure UVA-only systems are marketed as a safer alternative to the regular UVB-containing exposure, because the UVA is "gentler" in regard to burningTo the detriment of our people and their health, advertising focuses on burning risk rather than cancer death risk so as to be in compliance with FDA rulings against health claims (52).

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It would at this time be markedly unwise and detrimental to the health of the American Public to apply the proposed melanoma warning to garden-variety indoor tanning units. A broad view of the research suggests that such low-pressure UVA-UVB units are more likely to prevent melanoma than to cause it. A hypothetical case could be made for the high-pressure UVA-only units causing melanoma, but these are probably rendered innocuous by the body's accommodation mechanisms to this frequent regular exposure.

And also, I would like to make it clear that I have never received any financial support from any party in the indoor tanning industry. I am simply concerned with lowering cancer rates as much as possible.

Best Wishes.

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